106TH CONGRESS 2D SESSION

S. 2398

To amend the Public Health Service Act to revise and extend the programs relating to organ procurement and transplantation.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2000

Mr. FITZGERALD (for himself, Mr. SCHUMER, Mr. DURBIN, Mr. SANTORUM, Mr. SPECTER, Ms. MIKULSKI, Mr. SARBANES, and Mr. KERREY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to revise and extend the programs relating to organ procurement and transplantation.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Organ Transplantation
- 5 Fairness Act of 2000".
- 6 SEC. 2. FINDINGS.
- 7 (a) In General.—Congress makes the following
- 8 findings:

- (1) It is in the public interest to maintain and continually improve a national network to ensure the fair and effective distribution of organs among patients on the national waiting list irrespective of their place of residence or the location of the trans-plant program with which they are listed, and to en-sure quality and facilitate collaboration among net-work members and individual medical practitioners participating in the network activities.
 - (2) The Organ Procurement and Transplantation Network (referred to in this section as the "Network") was created in 1984 by the National Organ Transplant Act (Public Law 98–507) in order to facilitate an equitable allocation of organs among all patients on a national basis.
 - (3) The Federal Government should continue to provide Federal oversight of the Network and is responsible for protecting the public's health care interest and ensuring that the policies of the Network meet the goals established by this Act.
 - (4) The responsibility for developing, establishing, and maintaining medical criteria and standards for organ procurement and transplantation should be a function of the Network, and the Secretary of Health and Human Services should provide

- oversight to ensure compliance with this Act and ther applicable laws.
 - (5) The network should be operated by a private organization under contract with the Department of Health and Human Services.
 - (6) The Federal Government is responsible for ensuring that the efforts of the Network serve patients and donor families in the procurement and distribution of organs.
 - (7) The Federal Government should take immediate action to improve organ donation rates and increase the number of organs available for transplantation.
 - (8) There is a significant disparity between the number of organ donors and the number of individuals waiting for organ transplants, and it is in the public's best interest to have a system of organ allocation that ensures that transplant candidates with similar severity of illness have similar likelihood of transplantation irrespective of their place of residence or the location of the transplant program with which they are listed.
- (b) Sense of Congress Regarding Organ Dona Tion.—It is the sense of Congress that—

	-
1	(1) the factors that impact organ donation
2	rates are complex and require a multifaceted ap-
3	proach to increase organ donation rates;
4	(2) the Federal Government should lead the na-
5	tional effort to increase organ donation and develop
6	programs with the transplant community to research
7	and implement a best practices approach to increas-
8	ing organ donation; and
9	(3) a generous contribution has been made by
10	each individual who has donated an organ to save a
11	life.
12	SEC. 3. ORGAN PROCUREMENT ORGANIZATIONS.
13	Section 371 of the Public Health Service Act (42
14	U.S.C. 273) is amended to read as follows:
15	"SEC. 371. ORGAN PROCUREMENT ORGANIZATIONS.
16	"(a) Authority of the Secretary.—The Sec-
17	retary may make grants to, and enter into contracts with,
18	qualified organ procurement organizations described in
19	subsection (b), and other nonprofit private entities, for the
20	purpose of carrying out special projects designed to in-
21	crease the number of organ donors.
22	"(b) Qualified Organizations.—
23	"(1) Requirements.—A qualified organ pro-
24	curement organization for which grants may be

made under subsection (a) is an organization that,

1	as determined by the Secretary, will carry out the
2	functions described in paragraph (2), and that—
3	"(A) is a nonprofit entity;
4	"(B) has accounting and other fiscal proce-
5	dures (as specified by the Secretary) necessary
6	to ensure the fiscal stability of the organization;
7	"(C) has an agreement with the Secretary
8	to be reimbursed under title XVIII of the Social
9	Security Act for the procurement of kidneys;
10	"(D) notwithstanding any other provision
11	of law, has met the other requirements of this
12	subsection and has been certified or recertified
13	by the Secretary as meeting the performance
14	standards to be a qualified organ procurement
15	organization through a process that—
16	"(i) granted certification or recertifi-
17	cation within the previous 4 years with
18	such certification in effect as of October 1,
19	2000, and remaining in effect through the
20	earlier of—
21	"(I) January 1, 2002; or
22	"(II) the completion of recertifi-
23	cation under the requirements of
24	clause (ii); or

1	"(ii) is set forth in regulations pre-
2	scribed by the Secretary not later than
3	January 1, 2002, that—
4	"(I) require recertifications of
5	qualified organ procurement organiza-
6	tions not more frequently than once
7	every 4 years;
8	"(II) rely on outcome and proc-
9	ess performance measures that are
10	based on available, practical empirical
11	evidence of organ donor potential or
12	other related factors in each service
13	area of qualified organ procurement
14	organizations;
15	"(III) use multiple outcome
16	measures as part of the certification
17	process;
18	"(IV) provide for the filing and
19	approval of a corrective action plan by
20	a qualified organ procurement organi-
21	zation if the Secretary notifies the
22	organ procurement organization that
23	it has failed to meet the performance
24	measures after the first 2 years of the
25	4 year certification period, which cor-

1	rective action plan shall apply for the
2	3 years following approval of such
3	plan;
4	"(V) provide for a qualified
5	organ procurement organization to
6	appeal a decertification to the Sec-
7	retary on substantive and procedural
8	grounds;
9	"(E) has procedures to obtain payment for
10	nonrenal organs provided to transplant centers;
11	"(F) has a defined service area that is of
12	sufficient size to assure maximum effectiveness
13	in the procurement of organs;
14	"(G) has a director and other such staff,
15	including the organ donation coordinators and
16	organ procurement specialists necessary to ef-
17	fectively obtain organs from donors in its serv-
18	ice area; and
19	"(H) has a board of directors or an advi-
20	sory board that—
21	"(i) is composed of—
22	"(I) members who represent hos-
23	pital administrators, intensive care or
24	emergency room personnel, tissue

1	banks, and voluntary health organiza-
2	tions in its service area;
3	"(II) members who represent the
4	public residing in such area;
5	"(III) a physician with knowl-
6	edge, experience, or skill in the field
7	of histocompatibility or an individual
8	with a doctorate degree in biological
9	science with knowledge, experience, or
10	skill in the field of histocompatibility;
11	"(IV) a physician with knowledge
12	or skill in the field of neurology; and
13	"(V) from each transplant center
14	in its service area, a member who is
15	a surgeon who has practicing privi-
16	leges in such center and who performs
17	organ transplant surgery;
18	"(ii) has the authority to recommend
19	policies for the procurement of organs and
20	the other functions described in paragraph
21	(2); and
22	"(iii) has no authority over any other
23	activity of the organization.
24	"(2) Functions.—An organ procurement orga-
25	nization shall—

1	"(A) have effective agreements, to identify
2	potential organ donors, with all of the hospitals
3	and other health care entities in its service area
4	that have facilities for organ donation;
5	"(B) conduct and participate in systematic
6	efforts, including professional education, to ac-
7	quire all usable organs from potential donors;
8	"(C) arrange for the acquisition and pres-
9	ervation of donated organs and provide quality
10	standards for the acquisition of organs which
11	are consistent with the standards adopted by
12	the Organ Procurement and Transplantation
13	Network under section 372(b)(2)(F), including
14	arranging for testing with respect to preventing
15	the acquisition of organs that are infected with
16	the etiologic agent for acquired immune defi-
17	ciency syndrome;
18	"(D) arrange for the appropriate tissue
19	typing of donated organs;
20	"(E) assist the Organ Procurement and
21	Transplantation Network in the equitable dis-
22	tribution of organs among patients on a na-
23	tional basis;
24	"(F) provide or arrange for the transpor-
25	tation of donated organs to transplant centers;

1	"(G) have arrangements to coordinate its
2	activities with transplant centers in its service
3	area;
4	"(H) participate in the Organ Procure-
5	ment and Transplantation Network established
6	under section 372;
7	"(I) have arrangements to cooperate with
8	tissue banks for the retrieval, processing, pres-
9	ervation, storage, and distribution of tissues as
10	may be appropriate to assure that all usable tis-
11	sues are obtained from potential donors;
12	"(J) evaluate annually the effectiveness of
13	the organization in acquiring potentially avail-
14	able organs; and
15	"(K) assist hospitals in establishing and
16	implementing protocols for assuring that all
17	deaths and imminent deaths are reported to the
18	appropriate organ procurement organization.".
19	SEC. 4. ORGAN PROCUREMENT AND TRANSPLANTATION
20	NETWORK.
21	Section 372 of the Public Health Service Act (42
22	U.S.C. 274) is amended to read as follows:

1	"SEC. 372. ORGAN PROCUREMENT AND TRANSPLANTATION
2	NETWORK.
3	"(a) In General.—The Secretary shall by regula-
4	tion provide for the establishment and operation of an
5	Organ Procurement and Transplantation Network that
6	meets the requirements of subsection (b).
7	"(b) Requirements.—
8	"(1) In General.—The Organ Procurement
9	and Transplantation Network shall carry out the
10	functions described in paragraph (2) and shall—
11	"(A) be operated by a private entity under
12	contract with the Department of Health and
13	Human Services; and
14	"(B) have a board of directors—
15	"(i) not more than 50 percent of
16	which members are transplant surgeons or
17	transplant physicians;
18	"(ii) at least 25 percent of which
19	members are transplant candidates, trans-
20	plant recipients, organ donors, and family
21	members; and
22	"(iii) that includes representatives of
23	organ procurement organizations, vol-
24	untary health associations, and the general
25	public and

1	"(iv) that shall establish an executive
2	committee and other committees, whose
3	chairpersons shall be selected to ensure
4	continuity of the board.
5	"(2) Functions.—The Organ Procurement
6	and Transplantation Network shall—
7	"(A) establish and maintain one or more
8	lists derived from a national list of individuals
9	who need organ transplants;
10	"(B) establish a national system, through
11	the use of computers and in accordance with es-
12	tablished medical criteria, to match organs and
13	individuals included on such lists;
14	"(C) establish membership criteria for hos-
15	pitals, for performing organ transplants, and
16	for individual members;
17	"(D) maintain a 24-hour telephone service
18	to facilitate matching organs with individuals
19	included in such lists;
20	"(E) allocate organs so that transplant
21	candidates with similar severity of illness have
22	similar likelihood of receiving a transplant irre-
23	spective of their place of residence or the loca-
24	tion of the transplant program with which they
25	are listed;

1	"(F) adopt and use standards of quality
2	for the acquisition and transportation of do-
3	nated organs, including standards for pre-
4	venting the acquisition of organs that are in-
5	fected with the etiologic agent for acquired im-
6	mune deficiency syndrome;
7	"(G) prepare and distribute, on a national
8	basis, samples of blood sera from individuals
9	who are included on such lists in order to facili-
10	tate matching the compatibility of such individ-
11	uals with organ donors;
12	"(H) coordinate, as appropriate, the trans-
13	portation of organs from organ procurement or-
14	ganizations to transplant centers;
15	"(I) provide information to physicians and
16	other health professionals and the general pub-
17	lic regarding organ donation;
18	"(J) collect, analyze, and publish data con-
19	cerning organ donation and transplants;
20	"(K) provide data to the Secretary in order
21	to permit the Secretary to carry out the Sec-
22	retary's responsibilities under this part, and to
23	the Scientific Registry maintained pursuant to
24	section 373;

1	"(L) respond in a timely fashion and to
2	the extent permitted, to requests for data from
3	researchers and investigators;
4	"(M) carry out studies and demonstration
5	projects for the purpose of improving proce-
6	dures for organ procurement and allocation;
7	"(N) work actively to increase the supply
8	of donated organs;
9	"(O) submit to the Secretary an annual re-
10	port containing information on the comparative
11	costs and patient outcomes at each transplant
12	center affiliated with the Organ Procurement
13	and Transplantation Network; and
14	"(P) submit to the Secretary an annual re-
15	port containing such financial information, as
16	determined by the Secretary, to be necessary to
17	evaluate the cost of operating the Organ Pro-
18	curement and Transplantation Network.
19	"(3) Availability of patient listing fees
20	AND PARTICIPATION FEES.—
21	"(A) In general.—Any fees described in
22	subparagraph (B) that are collected by the
23	Organ Procurement and Transplantation
24	Network—

1	"(i) shall be available to the Organ
2	Procurement and Transplantation Net-
3	work, without fiscal year limitation, for use
4	in carrying out the functions of the Organ
5	Procurement Transplantation Network
6	under this section; and
7	"(ii) shall not be used for any activity
8	(including lobbying or other political activ-
9	ity) that is not authorized under this sec-
10	tion.
11	"(B) Covered fees.—Subparagraph (A)
12	applies with respect to the following:
13	"(i) Listing fees.
14	"(ii) Fees imposed as a condition of
15	being a participant in the Organ Procure-
16	ment and Transplantation Network.
17	"(C) Construction.—No provision of
18	this paragraph may be construed to prohibit the
19	Organ Procurement and Transplantation Net-
20	work from—
21	"(i) collecting fees other than the fees
22	described in subparagraph (B); or
23	"(ii) using fees covered by clause (i)
24	for an activity covered by subparagraph
25	(A)(ii) or other activity.

1	"(c) Organ Allocation.—
2	"(1) Development of Policies.—The Organ
3	Procurement and Transplantation Network shall de-
4	velop organ-specific policies (including combinations
5	of organs, such as for kidney-pancreas transplants)
6	subject to the review of and approval by the Sec-
7	retary, for the equitable allocation of cadaveric or-
8	gans to individuals on the national waiting list.
9	"(2) Listing Criteria.—Standardized min-
10	imum listing criteria for including individuals on the
11	national list shall be established and, to the extent
12	possible, shall—
13	"(A) contain explicit thresholds for the
14	listing of a patient;
15	"(B) avoid futile transplants or the wast-
16	ing of organs;
17	"(C) be expressed through objective and
18	measurable medical criteria; and
19	"(D) be reviewed periodically and revised
20	as appropriate.
21	"(3) REQUIREMENTS RELATING TO TRANS-
22	PLANT CANDIDATES.—Where appropriate for the
23	specific organ, transplant candidates shall—
24	"(A) be grouped by status categories from
25	most to least medically urgent with—

1	"(i) sufficient categories to avoid
2	grouping together individuals with substan-
3	tially different medical urgency;
4	"(ii) explicit thresholds for differen-
5	tiating among patients; and
6	"(iii) explicit standards for the move-
7	ment of individuals among the status cat-
8	egories;
9	"(B) be expressed through objective and
10	measurable medical criteria; and
11	"(C) be reviewed periodically and revised
12	as appropriate.
13	"(4) Requirements for allocation poli-
14	CIES AND PROCEDURES.—Organ allocation policies
15	and procedures shall be established in accordance
16	with sound medical judgment and shall—
17	"(A) be designed and implemented to allo-
18	cate organs among transplant candidates—
19	"(i) in order of decreasing medical ur-
20	gency status;
21	"(ii) over the largest geographic area
22	practicable in a manner consistent with
23	organ viability so that neither place of resi-
24	dence nor place of listing shall be a major
25	determinant; and

1	"(iii) so as to maintain organ viability
2	and avoid organ wastage; and
3	"(B) be reviewed periodically and revised
4	as appropriate.
5	"(5) Policies where medical urgency is
6	NOT AN APPROPRIATE MEASUREMENT.—Where med-
7	ical urgency is not an appropriate measurement for
8	organ allocation, policies and procedures shall be es-
9	tablished in accordance with sound medical judg-
10	ment.
11	"(d) Authority of the Secretary.—The policies
12	and rules established by the Organ Procurement and
13	Transplantation Network that are to be enforceable shall
14	be subject to review and approval by the Secretary. The
15	Secretary shall—
16	"(1) in consultation with the Organ Procure-
17	ment and Transplantation Network, develop mecha-
18	nisms to promote and review compliance with the re-
19	quirements of this section;
20	"(2) establish and approve all fees, dues, or
21	similar costs charged to support the operation of the
22	Organ Procurement and Transplantation Network;
23	"(3) establish procedures for receiving from in-
24	terested persons critical comments relating to the
25	manner in which the Organ Procurement and Trans-

- plantation Network is carrying out the duties of the
 Network under subsection (b); and
- "(4) take such action, as determined by the Secretary, to enforce the requirements of this section as well as the requirements under title XVIII of the Social Security Act.
 - "(5) if the Organ Procurement and Transplantation Network fails to submit a policy on a matter which the Secretary determines should be enforced under this section or section 1138 of the Social Security Act, or the Organ Procurement and Transplantation Network submits a policy that the Secretary determines is inconsistent with the goals of this Act, submit to the board of directors or advisory board of the Organ Procurement and Transplantation Network the Secretary's version of such policy.
 - "(e) National Transplant Advisory Board.—
 - "(1) ESTABLISHMENT.—The Secretary shall, by regulation, provide for the establishment of a National Organ Transplant Advisory Board (referred to in this subsection as the 'Board').
 - "(2) Membership.—The Board shall carry out the functions described in paragraph (3) and shall be comprised of individuals that—

1	"(A) include a broad spectrum of rep-
2	resentatives of the medical and scientific com-
3	munity, including transplant surgeons, trans-
4	plant physicians, epidemiologists, and health
5	service researchers, as well as representatives
6	from organ procurement organizations and the
7	community of transplant patients, family mem-
8	bers and donor families;
9	"(B) are selected by the Secretary;
10	"(C) serve terms of not less than 3 years.
11	"(3) Functions.—The Board shall assist the
12	Secretary in ensuring that the Organ Procurement
13	and Transplantation Network is grounded on the
14	best available medical science and is effective and
15	equitable as possible and shall—
16	"(A) at the request of the Secretary, re-
17	view the policies and rules of the Organ Pro-
18	curement and Transplantation Network;
19	"(B) advise and propose to the Secretary
20	policies, rules, and regulations affecting organ
21	procurement and transplantation;
22	"(C) at the request of the Secretary, re-
23	view and consider policies and regulations af-
24	fecting organ transplantation developed by the
25	Secretary;

1	"(D) advise the Secretary with respect to
2	comments received by the Secretary under sub-
3	section $(d)(3)$;
4	"(E) meet at the request of the Secretary,
5	but not less than 2 times each year; and
6	"(F) elect a Chairperson and Vice-chair-
7	person as well as any other officers as deter-
8	mined appropriate by the Board.
9	"(4) Authorization of appropriations.—
10	For the purpose of carrying out this subsection,
11	there are authorized to be appropriated \$1,000,000
12	for each of the fiscal years 2000 through 2005.".
13	SEC. 5. SCIENTIFIC REGISTRY.
14	Section 373 of the Public Health Service Act (42
15	U.S.C. 274a) is amended to read as follows:
16	"SEC. 373. SCIENTIFIC REGISTRY.
17	"The Secretary shall, by grant or contract, develop
18	and maintain a scientific registry of the recipients of organ
19	transplants. The registry shall include such information
20	concerning patients and transplant procedures as the Sec-
21	retary determines to be necessary to an ongoing evaluation
22	to the scientific and clinical status of organ transplan-
23	tation. The registry shall also include such information
24	concerning both donors and patients in transplants involv-
25	ing living donors. The Secretary shall prepare for inclusion

1	in the report under section 376 an analysis of information
2	derived from the registry.".
3	SEC. 6. ADMINISTRATION.
4	Section 375 of the Public Health Service Act (42
5	U.S.C. 274c) is amended to read as follows:
6	"SEC. 375. ADMINISTRATION.
7	"The Secretary shall designate and maintain an iden-
8	tifiable administrative unit in the Public Health Service
9	to—
10	"(1) administer this part and coordinate with
11	organ procurement activities under title XVIII of the
12	Social Security Act;
13	"(2) administer and coordinate programs, as
14	determined by the Secretary, to increase organ dona-
15	tion rates;
16	"(3) provide technical assistance to organ pro-
17	curement organizations, the Organ Procurement and
18	Transplantation Network established under section
19	372, and other entities in the health care system in-
20	volved in organ donations, procurements, and trans-
21	plants; and
22	"(4) provide information—
23	"(A) to patients, their families, and their
24	physicians about transplantation: and

"(B) to patients and their families about 1 2 resources available nationally and in each State, 3 and the comparative costs and patient outcomes 4 at each transplant center affiliated with the 5 Organ Procurement and Transplantation Net-6 work, in order to assist the patients and fami-7 lies with the costs associated with transplan-8 tation.". SEC. 7. ADDITIONAL AMENDMENTS. Part H of title III of the Public Health Service Act 10 11 (42 U.S.C. 273 et seq.) is amended— 12 (1) in section 374 (42 U.S.C. 274b)— 13 (A) in subsection (b)(1), by striking "and 14 may not exceed \$100,000" and inserting "and 15 other organizations for the purpose of increas-16 ing the supply of transplantable organs"; and 17 (B) in subsection (b)(2), by striking the 18 second sentence; 19 (2) in section 376 (42 U.S.C. 274d), by striking 20 "Committee on Energy and Commerce" and insert-21 ing "Committee on Commerce"; and 22 (3) by striking section 377 (42 U.S.C. 274f).

1	SEC. 8. PAYMENT OF TRAVEL AND SUBSISTENCE EXPENSES
2	INCURRED TOWARD LIVING ORGAN DONA-
3	TION.
4	Part H of title III of the Public Health Service Act
5	(42 U.S.C. 273 et seq.) is amended by inserting after sec-
6	tion 376 the following section:
7	"SEC. 376A. TRAVEL AND SUBSISTENCE PAYMENTS FOR
8	LIVING ORGAN DONATION.
9	"(a) In General.—The Secretary may make awards
10	of grants or contracts to States, transplant centers, quali-
11	fied organ procurement organizations under section 371,
12	or other public or private entities for the purpose of—
13	"(1) providing for the payment of travel and
14	subsistence expenses incurred by individuals toward
15	making living donations of their organs (referred to
16	in this section as 'donating individuals'); and
17	"(2) in addition, providing for the payment of
18	such incidental nonmedical expenses that are so in-
19	curred as the Secretary determines by regulation to
20	be appropriate.
21	"(b) Eligibility.—
22	"(1) In general.—Payments under subsection
23	(a) may be made for the qualifying expenses of a do-
24	nating individual only if—
25	"(A) the State in which the donating indi-
26	vidual resides is a different State than the

1	State in which the intended recipient of the
2	organ resides; and
3	"(B) the annual income of the intended re-
4	cipient of the organ does not exceed \$35,000
5	(as adjusted for fiscal year 2002 and subse-
6	quent fiscal years to offset the effects of infla-
7	tion occurring after the beginning fiscal year
8	2001).
9	"(2) Certain circumstances.—Subject to
10	paragraph (1), the Secretary may in carrying out
11	subsection (a) provide as follows:
12	"(A) The Secretary may consider the term
13	'donating individuals' as including individuals
14	who in good faith incur qualifying expenses to-
15	ward the intended donation of an organ but
16	with respect to whom, for such reason as the
17	Secretary determines to be appropriate, no do-
18	nation of the organ occurs.
19	(B) The Secretary may consider the term
20	'qualifying expenses' as including the expenses
21	of having one or more family members of do-
22	nating individuals accompany the donating indi-
23	viduals for purposes of subsection (a) (subject

to making payment for only such types of ex-

penses as are paid for donating individuals).

24

"(c) Limitation on Amount of Payment.—

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

"(1) IN GENERAL.—With respect to the geographic area to which a donating individual travels for purposes of section (a), if such area is other than the covered vicinity for the intended recipient of the organ, the amount of qualifying expenses for which payments under such subsection are made may not exceed the amount of such expenses for which payment would have been made if such area had been the covered vicinity for the intended recipient, taking into account the costs of travel and regional differences in the cost of living.

- "(2) COVERED VICINITY.—For purposes of this section, the term 'covered vicinity' with respect to an intended recipient of an organ from a donating individual, means the vicinity of the nearest transplant center to the residence of the intended recipient that regularly performs transplants of that type of organ.
- "(d) Relationship to Payments Under Other Programs.—An award may be made under subsection (a) only if the applicant agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that payment has been made, or can reasonably be expected to be made, with respect to such

25 expenses—

"(1) under any State compensation program, 1 2 under an insurance policy, or under any Federal or 3 State health benefits program; or "(2) by an entity that provides health services 4 5 on a prepaid basis. 6 "(e) Definitions.—In this section: "(1) COVERED VICINITY.—The term 'covered 7 8 vicinity' has the meaning given such term in sub-9 section (c)(2). "(2) Donating individual.—The term 'do-10 nating individual' has the meaning indicated for 11 12 such term in subsection (a)(1), subject to subsection (b)(2)(A).13 14 "(3) QUALIFYING EXPENSES.—The term 'quali-15 fying expenses' means the expenses authorized for 16 purposes of subsection (a), subject to subsection 17 (b)(2)(B). 18 "(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized 19 20 to be appropriated \$5,000,000 for each of fiscal years

2000 through 2005.".

1	SEC. 9. PROGRAMS AND DEMONSTRATION PROJECTS TO
2	INCREASE ORGAN DONATION.
3	Part H of title III of the Public Health Service Act
4	(42 U.S.C. 273 et seq.) is amended by inserting after sec-
5	tion 377 the following:
6	"SEC. 377A. INITIATIVES TO INCREASE ORGAN DONATION.
7	"(a) Public Awareness.—The Secretary shall (di-
8	rectly or through grants or contracts) carry out a program
9	to educate the public with respect to organ donation.
10	"(b) STUDIES AND DEMONSTRATIONS.—The Sec-
11	retary may make grants to public and nonprofit entities
12	for the purpose of carrying out studies and demonstration
13	projects with respect to increasing rates of organ donation.
14	The Secretary shall—
15	"(1) give priority to those studies and dem-
16	onstration projects that are founded upon a best
17	practices approach to increasing organ donation con-
18	sent rates;
19	"(2) give priority to those geographic areas
20	with lower organ donation consent rates, especially
21	among minorities;
22	"(3) provide assistance to qualified organ pro-
23	curement organizations described under section 371
24	to implement programs and projects, that as deter-
25	mined by Secretary through studies and demonstra-

1	tion projects, have proven to be effective in increas-
2	ing organ donation rates; and
3	"(4) provide assistance to the study and consid-
4	eration of presumed consent as an opportunity to in-
5	crease organ donation rates.
6	"(c) Grants to States.—The Secretary may make
7	grants to states for the purpose of carrying out public edu-
8	cation and outreach programs designed to increase the
9	number of organ donors within the State. To be eligible,
10	each State shall—
11	"(1) submit an application to the Secretary, in
12	such form as prescribed by the Secretary; and
13	"(2) establish yearly benchmarks for improve-
14	ment in organ donation rates in the State.
15	"(d) Congressional Medal.—
16	"(1) Design.—The Secretary shall design a
17	bronze medal with suitable emblems, devices, and in-
18	scriptions, to be determined by the Secretary, to
19	commemorate organ donors and their families.
20	"(2) Eligibility.—Any organ donor, or the
21	family of any organ donor, shall be eligible for a
22	medal under this subsection.
23	"(3) Requirements.—The Secretary shall di-
24	rect the Organ Procurement and Transplantation
25	Network, established under section 372, to—

1	"(A) establish an application procedure re-
2	quiring the relevant organ procurement organi-
3	zations, described in section 371, through which
4	an individual or their family made an organ do-
5	nation, to submit documentation supporting the
6	eligibility of that individual or their family to
7	receive a medal; and
8	"(B) determine through the documentation
9	provided, and, if necessary, independent inves-
10	tigation, whether the individual or family is eli-
11	gible to receive a medal.
12	"(4) Delivery.—The Secretary shall make
13	suitable arrangements as necessary with the Sec-
14	retary of the Treasury to strike and deliver the med-
15	als described in paragraph (3).
16	"(5) Presentation.—The Secretary shall pro-
17	vide for the presentation to the relevant organ pro-
18	curement organizations all medals struck pursuant
19	to this section to individuals or families that, in ac-
20	cordance with paragraph (3), the Organ Procure-
21	ment and Transplantation Network has determined
22	eligible to receive medals.
23	"(6) Limitation.—
24	"(A) IN GENERAL.—Except as provided in
25	subparagraph (B), only 1 medal may be pre-

1	sented to a family under paragraph (5). Such
2	medal shall be presented to the donating family
3	member, or in the case of a deceased donor, the
4	family member who signed the consent form au-
5	thorizing, or who otherwise authorized, the do-
6	nation of the organ involved.
7	"(B) Additional medals.—In the case
8	of a family in which more than 1 member is an
9	organ donor, an additional medal may be pre-
10	sented to each such organ donor or their family
11	"(7) Duplicates.—The Secretary or the
12	Organ Procurement and Transplantation Network
13	may provide duplicates of a medal—
14	"(A) to any recipient of a medal under
15	paragraph (4) under such regulation as the
16	Secretary may issue; and
17	"(B) the cost of which shall be sufficient
18	to cover the costs of such duplicates.
19	"(8) NATIONAL MEDALS.—The medals struck
20	pursuant to this subsection are national medals for
21	purposes of section 5111 of title 31, United States
22	Code.
23	"(9) Applicability of provisions.—No pro-
24	vision of law governing procurement or public con-
25	tracts shall be applicable to the procurement of

1	goods or services necessary for carrying out the pro-
2	visions of this subsection.
3	"(10) Funding.—
4	"(A) AGREEMENTS.—The Secretary of the
5	Treasury may enter into an agreement with the
6	Organ Procurement and Transplantation Net-
7	work to collect funds to offset expenditures re-
8	lating to the issuance of medals authorized
9	under this subsection.
10	"(B) Payment and Limitation.—
11	"(i) Payment.—Except as provided
12	in clause (ii), all funds received by the
13	Organ Procurement and Transplantation
14	Network under this paragraph shall be
15	promptly paid to the Secretary of the
16	Treasury.
17	"(ii) Limitation.—Not more than 5
18	percent of any funds received under this
19	paragraph may be used to pay administra-
20	tive costs incurred by the Organ Procure-
21	ment and Transplantation Network as a
22	result of an agreement established under
23	this subsection.
24	"(C) Deposits and expenditures.—
25	Notwithstanding any other provision of law—

1	"(i) all amounts received by the Sec-
2	retary of the Treasury under paragraph
3	(10)(A)(i) shall be deposited in the Numis-
4	matic Public Enterprise Fund, as de-
5	scribed in section 5134 of title 31, United
6	States Code; and
7	"(ii) the Secretary of the Treasury
8	shall charge such fund with all expendi-
9	tures relating to the issuance of medals au-
10	thorized under this subsection.
11	"(D) Start-up costs.—A one-time
12	amount of not to exceed \$55,000 shall be pro-
13	vided by the Secretary to the Organ Procure-
14	ment and Transplantation Network to cover ini-
15	tial start-up costs to be paid back in full within
16	3 years of the date of enactment of this section
17	from funds received under this subsection.
18	"(11) Definition.—For the purposes of this
19	section, the term 'organ' means the human kidney,
20	liver, heart, lung, pancreas, and any other human
21	organ (other than corneas and eyes) specified by
22	regulation by the Secretary.
23	"(12) Effective date.—This subsection shall
24	be effective for the 5-year period beginning on the
25	date of the enactment of this section.

- "(e) Annual Report to Congress.—The Sec-1 retary shall submit to the Congress an annual report on the activities carried out under this section, including pro-3 visions describing the extent to which the activities have 5 affected the rate of organ donation. 6 "(f) AUTHORIZATION OF APPROPRIATIONS.— 7 "(1) In general.—For the purpose of car-8 rying out this section, there are authorized to be ap-9 propriated \$10,000,000 for fiscal year 2000, and 10 such sums as may be necessary for each of the fiscal 11 years 2001 through 2005. Such authorization of ap-12 propriations is in addition to any other authoriza-13 tions of appropriations that are available for such 14 purpose. 15 "(2) Public Awareness.—Of the amounts ap-16 propriated under paragraph (1) for a fiscal year, the 17 Secretary may not obligate more than \$2,000,000 18 for carrying out subsection (a).".
- 19 SEC. 10. AUTHORIZATION OF APPROPRIATIONS.
- Section 378 of the Public Health Service Act (42)
- 21 U.S.C. 274g) is amended to read as follows:

- 1 "SEC. 378. AUTHORIZATION OF APPROPRIATIONS FOR
- 2 ORGAN PROCUREMENT AND TRANSPLAN-
- 3 TATION NETWORK.
- 4 "For the purpose of providing for the Organ Procure-
- 5 ment and Transplantation Network under section 372,
- 6 and for the Scientific Registry under section 373, there
- 7 are authorized to be appropriated \$4,000,000 for fiscal
- 8 year 2000, and such sums as may be necessary for each
- 9 of fiscal years 2001 through 2005.".
- 10 SEC. 11. PREEMPTION.
- 11 Part H of title III of the Public Health Service Act
- 12 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
- 13 tion 378 the following:
- 14 "SEC. 378A. PREEMPTION.
- 15 "No State or political subdivision of a State shall es-
- 16 tablish or continue in effect any law, rule, regulation, or
- 17 other requirement that would restrict in any way the abil-
- 18 ity of any transplant hospital, organ procurement organi-
- 19 zation, or other entity to comply with the organ allocation
- 20 policies of the Network under this part.".
- 21 SEC. 12. EFFECTIVE DATE.
- The amendments made by this Act shall take effect
- 23 on October 1, 2000, or upon the date of enactment of this
- 24 Act, whichever occurs later.